REMARKS

Claims 38 and 43 have been amended. New claims 49 and 50 have been added. Claims 1 to 37; 39; and 45 to 48 have been previously canceled.

Claims 38; 40 to 44; 49; and 50 remain in the application. Claim 38 is the sole independent method claim.

As defined in amended claim 38, a method for repairing a diseased or damaged section of an aorta comprises (i) providing a system comprising at least one tissue-piercing fastener having a sharpened distal tip for piercing and penetrating tissue, and a fastener attachment assembly sized and configured to be deployed from a remote access site to a targeted endovascular region. The fastener attachment assembly includes an intraluminal directing device defining an access path and including a deflectable distal region, and an intraluminal fastener applier separate from the intraluminal directing device. The separate intraluminal fastener applier is sized and configured for advancement into the intraluminal directing device along the access path and retrieval from the intraluminal directing device along the access path. The separate intraluminal fastener applier includes an actuated member that is selectively operable to generate an implantation force in an implantation force direction to implant the tissue-piercing fastener by causing the sharpened distal tip to pierce and penetrate the tissue in the targeted endovascular region. The fastener attachment assembly includes a means-plus-function element defined as means associated with the fastener attachment assembly for applying a resolving force in a direction different than the implantation force direction within the targeted endovascular region to resolve at least a portion of the implantation force.

Support for the means-plus-function language and the corresponding structures can be found, e.g., on Specification Page 23, line 9 to Page 26, line 32.

As further defined in amended claim 38, the method includes (ii) first, introducing the intraluminal directing device separately from intraluminal fastener applier from a remote access site to a location within a prosthesis that has been deployed at a target site in an aorta where the diseased or damaged section exists, and (iii) establishing the access path to a desired fastening site on the prosthesis by manipulating the intraluminal directing device within the prosthesis to orient the distal region with respect to the desired fastening site.

As further defined in amended claim 38, the method includes (iv) and then advancing the intraluminal fastener applier from the remote access site into the intraluminal directing device along the access path to the desired fastening site.

As further defined in amended claim 38, the method includes (v) anchoring the prosthesis by operating the actuated member to generate an implantation force to implant the tissue-piercing fastener into tissue at the desired fastening site while the means applies a resolving force to resolve within the targeted site within an aorta at least a portion of the implantation force.

As further defined in amended claim 38, the method includes (vi) and then separating the intraluminal fastener applier from the intraluminal directing device by retrieving the intraluminal fastener applier from the intraluminal directing device along the access path back to the remote access site.

The time and attention of Examiner Ryckman and Examiner Jackie Ho during an interview conducted February 20, 2008 are appreciated. During the interview, inventor Lee Bolduc discussed prior art approaches to the treatment of abdominal aortic aneurysms and attendant problems, e.g., (i) endograft migration (the endograft does not remain in position) including reliance upon radial force from a stent on the endograft and/or barbs or hooks on the endograft, which may not provide sufficient force to hold the device against blood flow, and (ii) the lack of control over barb or hook orientation, placement, and penetration in endovascular tissue. Mr. Bolduc discussed and, using video aids and by manipulating clinical devices brought to the interview, demonstrated a two component delivery system for tissue-piercing fasteners as defined in claim 38 (i.e., including an intraluminal directing device defining an access path, and an intraluminal fastener applier separate from the intraluminal directing device), which provide orientation of the fastener (i.e., an intraluminal directing device including a deflectable distal region), as well as provide a resolution of the implantation force within the targeted endovascular region (i.e., including means associated with the fastener attachment assembly for applying a resolving force in a direction different than the implantation force direction within the targeted endovascular region to resolve at least a portion of the implantation force). Mr. Bolduc demonstrated the operation of a clinical, two component system comprising an intraluminal directing device and an intraluminal fastener applier separate from the intraluminal directing device, as defined in claim 38. With the two component system, Mr. Bolduc simulated the method defined in claim 38 including (ii) first, introducing the intraluminal

directing device separately from intraluminal fastener applier from a remote access site to a location within a prosthesis that has been deployed at a target site in an aorta where the diseased or damaged section exists; (iii) establishing the access path to a desired fastening site on the prosthesis by manipulating the intraluminal directing device within the prosthesis to orient the distal region with respect to the desired fastening site; (iv) and then advancing the intraluminal fastener applier from the remote access site into the intraluminal directing device along the access path to the desired fastening site; (v) anchoring the prosthesis by operating the actuated member to generate an implantation force to implant the tissue-piercing fastener into tissue at the desired fastening site while the means applies a resolving force to resolve within the targeted site within an aorta at least a portion of the implantation force; (vi) and then separating the intraluminal fastener applier from the intraluminal directing device by retrieving the intraluminal fastener applier from the intraluminal directing device along the access path back to the remote access site.

During the interview, a draft Amendment D was discussed in view of the standing rejection of the claims under 35 U.S.C 103(a) based upon Taheri et al. (US 5,042,707). Applicant pointed out that Taheri does not teach or suggest an intraluminal directing device defining an access path, and an intraluminal fastener applier separate from the intraluminal directing device, as defined in amended claim 38. In Taheri, the fastener applier cannot be advanced into the directing device and separated from the directing device by retrieval from the directing device, as defined in claim 38. Taheri also does not teach or suggest or comprehend the concept of force resolution. A look at Fig. 12 of Taheri bears this out – Taheri is oblivious to the fact that the implantation force of the fastener applier needs to be resolved in some manner within the vessel or hollow body organ to provide positional stability and resist unintended movement of the fastener applier relative to the implantation site. Mr. Bolduc described his recognition – not contemplated by the prior art -- that the implantation force of the fastener applier needs to be resolved in some manner within the vessel or hollow body organ, to provide positional stability and resist unintended movement of the fastener applier relative to the implantation site. As explained by Mr. Bolduc, a resolution force needs to be applied to counteract and/or oppose the implantation force of the fastener applier. These matters are also described in the Specification, pages 23 to 26.

At the conclusion of the interview, the Examiners indicated that agreement was reached with respect to claim 38, subject to the applicant's clarification of elements (ii) and (vi) in claim 38. Applicant agreed to clarify claim 38 in these respects.

It is believed that the foregoing amendment to claim 38 accomplishes this. Claim 38, as amended, further emphasizes that the intraluminal fastener applier is separate from the intraluminal directing device by defining, in (ii) first, introducing the intraluminal directing device separately from intraluminal fastener applier from a remote access site to a location within a prosthesis that has been deployed at a target site in an aorta where the diseased or damaged section exists, and, in (iv) and then separating the intraluminal fastener applier from the intraluminal directing device by retrieving the intraluminal fastener applier from the intraluminal directing device along the access path back to the remote access site.

For these reasons, applicant believes that Claims 38; 40 to 44; 49; and 50 are in condition for allowance. As expressed during the interview, if the Examiner believes that questions or matters of clarification remain, applicant believes that such matters can be handled expeditiously by an interview by telephone to advance prosecution of this case, and the applicant remains committed to proceed on that basis.

Respectfully Submitted,

By_____

Daniel D. Ryan
Registration No. 29,243

RYAN KROMHOLZ & MANION, S.C.
Post Office Box 26618
Milwaukee, Wisconsin 53226
(262) 783 - 1300
Customer No.: 26308